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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,015

04/18/2006

Claudio Soto-Jara

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SALIWANCHIK LLOYD & SALIWANCHIK

A PROFESSIONAL ASSOCIATION

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EXAMINER

STOICA, ELLY GERALD

ART UNIT

PAPER NUMBER

1647

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,015	<b>Applicant(s)</b> SOTO-JARA ET AL.	
	<b>Examiner</b> ELLY-GERALD STOICA	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 95-104, 106-131 and 133-138 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 95-104, 106-131 and 133-138 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Amendment***

***Status of the claims***

1. In the amendment submitted on 04/14/2009 Applicant has canceled claims 105 and 132 and amended claims 95, 97, 100, 104, 106-108, 111,114, 118-122, 124, 127, 131, 133, 134, and 135. Claims 95-104, 106-131 and 133-138 are pending and are currently examined.

***Withdrawn objection and claim rejections***

2. The objection to claim 97 is withdrawn in view of the amendment to the claim.

3. The rejection of claims 95-97, 100, 104, 106, 107, 109, 110, 111, 113-114, 120, 121,123, 124 126-127, 133, 134, 136, and 138 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment to the claims.

4. The rejection of claim 138 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of the Applicant's persuasive arguments.

5. The rejection of claims 95-97, 99-100, 102-104, 106-111, 113-114, 116-118, 120-124, 126-127, 129-130 and 133 -138 under 35 U.S.C. 112, first paragraph, scope of enablement is withdrawn in view of the persuasive arguments of the Applicant.

***Maintained claim rejections***

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 95-104, 106-131 and 133-136 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Godfrey et al. (U.S. Pat. 6,242,566 -cited in the prior Office action) in view of Chien et al. (Proc. Natl. Acad. Sci. USA, 88, 9578-9582, 1991-cited in the prior Office action) for reasons of record.

On page 14 of the Remarks Applicant argues that the Invention is not obvious over prior art and that the examiner's conclusion of obviousness is based upon improper hindsight reasoning. The arguments were carefully considered but not found persuasive because it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). To address Applicant's argument, it needs to be pointed out that the polypeptide of Seq. Id. No.: 6 of the instant Application is 100% identical with the amino acid string 94-124 of the Seq. Id. No.: 4 of Godfrey et al. Also, SEQ ID NO: 6 of the instant Application comprises the SEQ ID NO: 8 and 13 and these sequences would have been found by applying the teachings of the references cited.

Art Unit: 1647

Thus the Sequence of Godfrey contains the three sequences claimed in the instant Application. Moreover, the instant claims are not limited in to particular sequences because the independent claim 95 contains the limitation “derivative”, which allows a broader interpretation of the claims. Applicant further argues (p.15) that “absent the teachings of the as-filed specification, one skilled in the art would not have expected small linear peptides would have had the ability to bind to OX40R and antagonize the activity of the receptor and/or its interaction with OX40L.” The arguments were carefully considered but not found persuasive because as iterated previously, the two hybrid system of Chien et al. would have easily identified the binding motif of the ACT-4-h-1 of Godfrey et al. to its receptor. This is because in the art, at the time the invention was made, it was customary to use small peptides for antagonizing the receptors as evidence for example by the U. S. Pat. No. 5,866,681 (Scarborough RM- which teach small peptides and peptide derivatives that bind to cellular thrombin receptors and inhibit the activation of the receptor induced by thrombin. The peptide derivatives offers a greater improvement in therapeutic potential since the structure of peptide derivatives of this type renders them less susceptible to proteolytic inactivation-col. 3, line 65 to col. 4, line 5). Another evidentiary reference for the state of the art and is U.S. Pat. No. 6,872,519 (Sokoloff et al. – which teaches that libraries of small peptides have been routinely used to map epitopes, protein--protein interactions, protease inhibitors, integrin ligands, and receptor agonists and antagonists- col. 15, lines 26-42). Therefore the argument that there would not have been any motivation to look for a linear peptide with the method of Chien et al. is not persuasive since the art was well aware of using small

Art Unit: 1647

peptides (linear peptides) as receptor antagonists. The motivation is always present to a skilled artisan that uses known options available to him to optimize a process or a formulation, as eloquently expressed in the Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 550 US, 82 USPQ2d 1385 (2007).

8. Claim 137 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Godfrey et al. (U.S. Pat. 6,242,566 -cited in the prior Office action) in view of Chien et al. (Proc. Natl. Acad. Sci. USA, 88, 9578-9582, 1991-cited in the prior Office action), and Hruby et al. (Curr. Med. Chem. 7,945-970, 2000- cited in the Application) for the reasons of record.

On page 15 of the Remarks Applicant argues that the invention is not obvious of the prior art since the Hruby et al. reference does not cure the alleged deficiencies of the combined references of Godfrey et al. and Chien et al. The arguments were carefully considered but not found persuasive and were responded to above. Therefore, the claim remains rejected. No separate argument pertaining to the Hruby reference is presented.

9. Claim 138 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Godfrey et al. (U.S. Pat. 6,242,566 -cited in the prior Office action) in view of Chien et al. (Proc. Natl. Acad. Sci. USA, 88, 9578-9582, 1991-cited in the prior Office action) and Quillan et al. (U.S. Pat. No. 6,602,856- cited previously) for the reasons of record.

On page 15 of the Remarks Applicant argues that the invention is not obvious of the prior art since the Quillan et al. reference does not cure the alleged deficiencies of

Art Unit: 1647

the combined references of Godfrey et al. and Chien et al. The arguments were carefully considered but not found persuasive and were responded to above. Therefore, the claim remains rejected. No separate argument pertaining to the Quillan reference is presented.

### ***Conclusion***

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is

Art Unit: 1647

(571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/

Primary Examiner, Art Unit 1647